

## **REMARKS**

Entry of this paper and consideration of the subject application in view thereof are respectfully requested.

### ***I. Status Of Claims***

Claims 44-63 were pending in this application and these claims stood rejected. Claims 44-63 have been canceled and new claims 64-77 have been presented to clarify the invention. Support for the process involving montelukast dicyclohexylamine salt (X) as set forth in claim 64 can be found in the specification, for example, at page 13, lines 1-19. Support for the process for the isolation of montelukast acid as recited in claim 70 can be found in the specification, for example, at page 20, Example 3, and at page 13, line 20 through page 14, line 4. Support for the process directed to the preparation of montelukast sodium in an amorphous form as recited in claim 76 can be found in the specification, for example, at page 21, Example 4, and at page 16, lines 11-21. No new matter is added.

### ***II. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph***

Claims 47, 48, 53 and 54 stood rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully submits that this rejection is moot in view of the revised claims presented herein. Accordingly, Applicant respectfully requests reconsideration and removal of the rejection under 35 U.S.C. § 112, second paragraph.

### ***III. Rejection Under 35 USC § 102***

Claims 44-63 stood rejected under 35 U.S.C. § 102(b) as being anticipated by Bhupathy et al., U.S. Patent 6,320,052 ("Bhupathy"). Applicant respectfully submits that this rejection is moot in view of the revised claims presented herein. To the extent the Examiner wishes to maintain the rejection based on the Bhupathy patent, however, Applicant respectfully traverses the rejection.

A prior art reference anticipates a patent claim if the reference discloses, either expressly



or inherently, all of the limitations of the claim. *Bristol-Myers Squibb v. Ben Venue*, 246 F.3d 1368 (Fed. Cir. 2001); *Schering Corporation v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003); *See also, M.P.E.P. §2131 citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible, Inc.*, 230 USPQ 81 (Fed. Cir. 1986).

Bhupathy teaches a process for the preparation of a compound of formula (I) or a dicyclohexylamine salt of a compound of formula (I).

Independent claim 64 is directed to a process involving montelukast dicyclohexylamine salt (X), independent claim 70 is directed to a process for the isolation of montelukast acid, and claim 76 is directed to a process for the preparation of montelukast sodium in amorphous form. Applicant respectfully believes that the Examiner's statement, at page 6 of the Office Action, that "[t]he desired product, montelukast sodium (I), was recovered in greater than 99+% yield (see column 21, lines 23-31)" is believed to be in error because the Example 14 of which the cited text is part of, is not about montelukast sodium (I). Further, Bhupathy does not teach or disclose any process involving montelukast dicyclohexylamine salt (X) or montelukast acid or montelukast sodium in amorphous form. Furthermore, Bhupathy does not teach or disclose the specific process steps involving montelukast dicyclohexylamine salt (X) or montelukast acid or montelukast sodium in amorphous form. Because Bhupathy fails to teach or disclose each and every limitation of claims 64, 70 and 76, Bhupathy cannot anticipate independent claims 64, 70 and 76. The dependent claims at least by virtue of their dependency from their respective independent claims are similarly considered by Applicant to patentably define themselves over the Bhupathy reference. As such, claims 64-77 stand in condition for allowance for these very same reasons. Reconsideration and withdrawal of this rejection are respectfully requested.



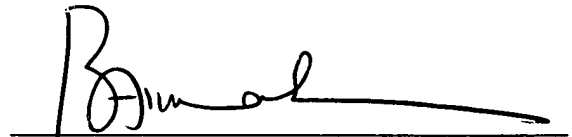
**IV. Conclusion**

Applicant believes this response to be a full and complete response to the Office Action. Accordingly, favorable reconsideration in view of this response and allowance of all of the pending claims are earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Date: May 26, 2009

Respectfully submitted,



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